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Title: Development of a non-invasive diagnostic technique for acetabular component loosening in total hip replacements

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Abstract

Current techniques for diagnosing early loosening of a total hip replacement (THR) are ineffective, especially for the acetabular component. Accordingly, new, accurate, and quantifiable methods are required. The aim of this study was to investigate the viability of vibrational analysis for accurately detecting acetabular component loosening.

A simplified acetabular model was constructed using a Sawbones® foam block. By placing a thin silicone layer between the acetabular component and the Sawbones block, 2- and 4-mm soft tissue membranes were simulated representing different loosening scenarios. A constant amplitude sinusoidal excitation with a sweep range of 100–1500 Hz was used. Output vibration from the model was measured using an accelerometer and an ultrasound probe. Loosening was determined from output signal features such as the number and relative strength of observed harmonic frequencies.

Both measurement methods were sufficient to measure the output vibration. Vibrational analysis reliably detected loosening corresponding to both 2 and 4 mm tissue membranes at driving frequencies between 100 and 1000 Hz ($p < 0.01$) using the accelerometer. In contrast, ultrasound detected 2-mm loosening at a frequency range of 850–1050 Hz ($p < 0.01$) and 4-mm loosening at 500–950 Hz ($p < 0.01$).

Keywords:

Total hip replacement (THR), Acetabular cup loosening, Vibrational technique, Loosening diagnostic, Ultrasound, Accelerometer

1. Introduction

One million total hip replacement (THR) operations are conducted annually worldwide, and this number is predicted to increase [1]. Within the first ten years of THR, around 10% of all implants are expected to fail, with loosening being the most common reason [2]. The diagnostic approaches to detect loosening are generally categorised into two groups: imaging and non-imaging approaches [3].

Radiology is the most commonly used diagnostic method and consists of different sub-techniques that can be used depending upon need. These techniques generally inspect the bone and implant interfaces to identify osseointegration, failure, or fractures [4]. However, due to the diffraction effects associated with x-ray scattering, it may be difficult to diagnose early loosening using radiological imaging techniques, especially for the acetabular component [5, 6]. Even though imaging has a sensitivity and specificity of up to 80% for loosening detection, revision operations on a well-fixed implant may still occur [7].

Vibration analysis is a mechanical non-destructive technique that is widely used to inspect composite materials and structural integrity, and it has been successfully expanded into the arena of biomechanics [5]. This technique predominantly measures the response to low-frequency excitation that is reflected from the targeted surface or structure [8]. In the early 1930s, Lippmann [9] pioneered vibration analysis in medical research, utilising the stethoscope to examine bone fractures and using his fingers to elicit the input vibration. As technology developed, research groups had better tools at their disposal to investigate and develop a clinical diagnostic instrument; this was realised in the works of Chung et al. [10] and Poss et al. [11], who used vibration analysis to study the process of prosthetic fixation using bone cement. They implied that by using vibration analysis and monitoring the resonance frequency shift phenomena, it is possible to estimate implant fixation states. In this scenario, the implant osseointegration process is reflected by a gradual increase in the frequency response. Further studies also were conducted [12-19] to measure the dynamic properties of the implant in order to identify different interference changes.

Rosenstein et al. [20] were one of the first groups to utilise vibration analysis both *in vivo* and *in vitro* in a clinical study. They showed that a secure prosthesis would respond with a single frequency vibration, whereas a loose prosthesis would vibrate at different frequencies appearing as different peaks in the frequency spectrum; this vibration analysis concept is simplified for the acetabular component, as presented in Figure 1.

Li et al. [21, 22] were the next to explore vibration analysis, showing that the early prosthetic loosening diagnosis has a poor sensitivity (37.5%), but that it could reliably detect late loosening. Georgiou and Cunningham [23] also compared vibration analysis with standard radiological assessment and demonstrated that vibration analysis improved diagnostic precision by 20%; moreover, they were able to detect 13% more cases than radiological diagnosis with 81% sensitivity and 89% specificity. Other research groups have used vibration analysis for different orthopaedic applications such as; the telemetry technique to assess THR femoral loosening [24-26], trans-femoral osseointegration [27-29], intra-operative initial implant stability [6,30-33], THR femoral stability utilising acoustic resonance responses [7, 34-41], and complete THR component loosening (femoral and acetabular) [5].

Rowlands et al. [42] investigated replacement of the accelerometer sensor with an ultrasound probe to overcome the effect of soft tissue damping. Their approach used excitation frequencies < 1500 Hz on two different types of bone analogues, Sawbones® and Tufnol®. Initially, the Sawbones femur was tested with both a fixed and loose hip prosthesis by using cement fixation. The Tufnol femur was then tested for three interface conditions by using different diameter solid bars of varied fits (fixed, sliding, and loose). Ultrasound distinguished between the secure and loose states with a noticeably higher signal magnitude than the accelerometer.

The majority of previous studies on vibration analysis [20-24, 35-42] assessed loosening of the femoral stem. Since a high rate of loosening in the acetabular component has been reported in the clinically [43]; therefore, the aim of the present study was to compare ultrasound and accelerometer methods and to examine the viability of the vibration analysis technique to accurately detect acetabular component loosening.

2. Materials and methods

A simplified model was constructed to mimic different scenarios of acetabular cup loosening. A secure component was represented by a tight press-fit of the acetabular cup in polyurethane solid foam (Sawbones) blocks with a hemispherical cavity. By placing a thin layer of low modulus silicone (EVO-STIK, Bostik Limited, England) between the acetabular component and the Sawbones block, the loosening effects of 2 and 4 mm soft tissue interfaces were simulated. To represent healthy bone density, blocks with a density of 0.48 g/cm^3 (Sawbones Europe AB, Malmö, Sweden) were used, with two acetabular cups having outside diameters of 54 and 52 mm, respectively (Trident® Hemispherical cup, Stryker Orthopaedics, Mahwah, New Jersey, USA), as shown in Figure 2.

The secure Sawbones block cavity (diameter 53 mm) was machined using a computer numerically controlled (CNC) milling machine. Subsequent cavities to simulate loosening were created using acetabular reamers to give cup cavity diameters of 56 and 60 mm. This created a gap between the cup shell and the block cavity surface, as shown in Figure 3. The secure acetabular cup scenario (0-mm loosening) involved using the 54-mm acetabular cup press-fitted in a 53-mm diameter Sawbones block cavity until it was immovable. The 2- and 4-mm loose cup scenarios were produced using the 52-mm acetabular cup placed into Sawbones blocks with cup cavity diameters of 56 and 60 mm, respectively, as shown in Figure 3. In both loosening scenarios, a silicone layer between the acetabular cup and the Sawbones interface was used to mimic the soft tissue interface in accordance with previous studies [21, 22]. Each scenario was exposed to a vibration sweep range of 100–1500 Hz using a mini shaker (V201, LDS Ltd, UK). The Sawbones block setup was lightly suspended to create a repeatable boundary condition, (Figure 4a).

2.1 Excitation Signal

A function generator (TG230, Thurlby Thandar Ltd, UK) connected to a power amplifier (PA25E, LDS Ltd, UK) was used for vibration excitation via a mini-shaker (V201, LDS Ltd, UK). The excitation signal was a constant amplitude sinusoidal wave with a frequency sweep range of between 100 and 1500 Hz, with incremental steps of 50-Hz. The shaker was positioned in a similar location on the Sawbones block for all tests (Figure 4b).

2.2 Measurement and analysis

An ultrasound transducer (Mini Dopplex 500 4 MHz, Huntleigh Technology Plc, UK) and accelerometer (Model 353B18; PCB Piezotronics Inc, US) were used to measure the output vibration. Consistent with other orthopaedic vibration studies [5, 20-23], the accelerometer was used as a reference measurement method. Ultrasound was chosen as an alternative measurement method due to its capacity to overcome the attenuating effect of the soft tissues surrounding the implant in the clinical environment [42].

The ultrasound and accelerometer data were recorded using a custom code in LabVIEW (Sound and Vibration Measurement Suite version 11, National Instruments) via a USB data acquisition system (USB-4431, National Instruments) using a personal computer (Core2Duo 3.16 GHz, CPU 4 GB RAM). The resulting natural frequency spectrum of both measurement methods was then observed using a fast Fourier transform (FFT) to define the optimum frequency excitation range using two simultaneous measurement methods; twelve measurements were obtained at 50-Hz increments from each of the fixation scenarios (0-, 2-, and 4-mm loose) under the sinusoidal frequency sweep. Insufficient sampling frequency may result in distortion from the original continuous signal, which is known as the aliasing effect. Thus, a sampling frequency of 8 kHz was used to overcome this effect. The accelerometer was coupled to the block surface using a petro-wax, and ultrasound gel was used to couple the ultrasound probe. Each measurement was taken from a specifically defined location on the Sawbone block for accuracy and repeatability (Figure 4). Analysis was conducted in two stages as explained below: the spectrum analysis and the harmonic ratio.

2.2.1 Spectrum Analysis

Real-time spectrum analyses tracked the frequency response and observed relationships between the two loosening scenarios and the secure condition across the different driving frequencies. For the secure implant, vibration analysis implies that the frequency response would be similar to the excitation signal, whereas for the loose condition, the response would be distorted with multiple apparent harmonics. This was accomplished using two frequency variables: the fundamental frequency (F_o) and the first harmonic (F_1). The main response to the driving frequency is the fundamental frequency, whereas the first harmonic is indicative of system nonlinearity.

2.2.2 Harmonic Ratio

In an attempt to define the optimum frequency excitation range for the loosening assessment, a sweep analysis was conducted. The resulting frequencies were then analysed as the harmonic ratio, defined as the relative magnitude of the first harmonic to the fundamental frequency (Harmonic Ratio = First Harmonic [F_1] magnitude/Fundamental Frequency [F_o] magnitude). This ratio can then be utilised to show how the different loosening conditions affect the relative magnitude of the first harmonic across the different driving frequencies.

2.3 Statistics

Statistical analysis was performed using SPSS software (version 20.0; SPSS, Chicago, IL, USA). A Shapiro-Wilk test revealed that the harmonic ratio data were not normally distributed; thus, non-parametric analyses were performed. The conditions (0, 2, and 4 mm) were compared at each frequency step using a Kruskal-Wallis test, and Mann-Whitney U-tests were used for post-hoc analysis. Significance was defined as a p value of <0.05.

3. Results

3.1 Spectrum analysis

The initial variable in the FFT spectrum analysis was the fundamental frequency (F_o) magnitude that changed in relation to the cup stability. The frequency magnitude was assessed based on the root mean squared (RMS) value over the excitation period. Figure 5 shows the output measurement response of three simulated loosening conditions at a driving frequency of 200 Hz for both the ultrasound and accelerometer. It was noted that the secure condition had the highest fundamental frequency magnitude, followed by the 2- and 4-mm loose conditions, respectively. However, when examining the readings for both the ultrasound and accelerometer, the absolute magnitude of the reduction in vibration magnitude with loosening is higher for the ultrasound readings than for the accelerometer readings, as shown in Figure 5.

The next variable examined was the first harmonic (F_1), which behaves in a manner opposite to the fundamental frequency (F_o). The magnitude of the first harmonic peak increased relative to the degree of acetabular cup loosening. For example, in Figure 5, the first harmonic with 4-mm loosening had a higher magnitude than for 2-mm loosening. When comparing the absolute magnitude of the first harmonic using the two measurement methods, the ultrasound results were able to discern more harmonics than the accelerometer results, enabling a clear distinction between the loosening scenarios.

The above findings indicated that as the gap between the Sawbones block and cup increased (representing increased loosening), the system became more non-linear, which was reflected in the lower fundamental frequency and higher harmonic peak values. These harmonic readings correlated with the finding of Rowlands et al. [42], who reported that the presence of harmonics can be used as an indication of loosening, which could be detected using either the accelerometer or ultrasound transducers , especially for frequencies < 500 Hz with stem component .

3.2 Harmonic ratio

The harmonic ratio measurement for the three simulated conditions by using ultrasound and accelerometer was illustrated alongside each other using the median ± 95% confidence interval for ease of comparison. The Mann-Whitney test was used to determine significance (defined as $p < 0.05$), as shown in Figure 6.

3.2.1 Accelerometer

The harmonic ratios for the accelerometer are shown in Figure 6a. The ratios clearly showed a pattern, according to which the secure cup had the lowest value, followed by 2-mm loosening, and 4-mm loosening having the highest harmonic ratio in the frequency range up to 950 Hz. The harmonic ratio for 2-mm loosening was significantly greater ($p < 0.01$) than that in the secure condition in the driving frequency range 100–1050 Hz (Figure 6c). For 4-mm loosening, the harmonic ratio was significantly greater ($p < 0.01$) than that in the secure condition in the frequency range 100–1000 Hz (Figure 6e). When comparing the two loosening conditions, the 4-mm loosening condition resulted in a significantly higher harmonic ratio ($p < 0.05$) in the frequency ranges 150–250 Hz and 550–900 Hz.

3.2.2 Ultrasound

The harmonic ratio derived from ultrasound measurements had a higher magnitude than the accelerometer readings, as shown in Figure 6 a-b. The ultrasound measurements were between 200 and 1500 Hz due to the ultrasound system’s built-in filter that affected readings below 200

Hz. The same pattern was observed with the accelerometer, with the lowest harmonic ratio observed in the secure condition and progressively increasing at 2- and 4-mm loosening, respectively. The 2-mm loosening resulted in a significantly higher harmonic ratio ($p < 0.01$) than that in the secure condition at driving frequencies between 850 and 1050 Hz (Figure 6d). The harmonic ratio of the 4-mm loosening condition was significantly higher ($p < 0.01$) than that in the secure condition between 500 and 950 Hz (Figure 6f). The harmonic ratio for 4-mm loosening was significantly greater ($p < 0.05$) than that for 2-mm loosening between 500 and 700 Hz and between 800 and 850 Hz.

4. Discussion

Most THR stability assessment studies have focused on the femoral component [20-24, 35-42]. Vibration analysis studies on acetabular loosening are limited because the acetabulum has a complex geometry compared to the femur and has a thicker overlaying soft tissue layer, which acts as a signal buffer. Thus, the aim of this study was to explore the viability of vibration analysis to accurately detect acetabular component loosening.

Vibration analysis implies that secure implants respond with a single frequency peak similar to the excitation signal, whereas loose implants vibrate at different frequencies, which appear as multiple harmonics peaks in the frequency spectrum. The resulting frequencies were initially observed using FFT analysis, then analysed as the harmonic ratio, which was subsequently used as a novel method to track frequency responses and observe relationships between the loosening scenarios and the secure condition across frequencies of 100–1500 Hz. Using this approach, the three simulated conditions were distinguishable at an excitation frequency range of 200–950 Hz, using both ultrasound and the accelerometer.

Most orthopaedic vibration studies have used FFT spectrum analysis to assess implant loosening [20-23, 42]. However, most examined the stem component and reported that implant instability can be identified through harmonics in the frequency spectrum (Figure 1). Moreover, they highlighted that the lower frequency range (≤1000 Hz) had the most potential for stability assessment [20, 23]. Rieger et al. [5] assessed a complete THR (femoral and acetabular implants in a Sawbones femur and hemi-pelvis) and detected acetabular cup loosening at frequencies of 450 and 600 Hz. At these frequencies, a noticeable resonance shift was observed when the loosening condition was compared with the secure condition using an accelerometer and laser vibrometer. Using an FFT analysis, the present study revealed the same overall conclusions. The difference between the three simulated conditions was observed using two frequency variables: the fundamental frequency (F_o) and the first harmonic (F_1). The fundamental frequency was primarily in response to the driving frequency, and the first harmonic indicated the level of instability. The three simulated conditions examined with FFT analysis at a driving frequency of 200 Hz demonstrated that, as loosening increases, the system becomes increasingly non-linear, which is reflected at the lower fundamental frequency and higher harmonic peak magnitude (Figure 5).

Another novel contribution of this study is the use of the harmonic ratio to quantify the FFT spectrum analysis frequency response across the 100–1500 Hz range. This ratio represents the relative magnitude of the first harmonic to the fundamental frequency. When analysing the harmonic ratio for the accelerometer and ultrasound measurements at frequencies < 950 Hz, a clear pattern was observed. The secure cup had the lowest ratios and, as the loosening progressed, this ratio increased. At excitation frequencies of 100–1050 Hz, the accelerometer detected loosening corresponding to 2 mm between the cup shell and the Sawbones surface, while 4 mm loosening was detected at excitation frequencies of 100–1000 Hz. In agreement with the study of Rowlands et al. [42] which examined stem loosening, as opposed to acetabular loosening in the current study, the ultrasound measurements were clearly higher than accelerometer readings throughout the frequency range. However, because of the increased variability of ultrasound measurements compared to measurements with the accelerometer, a significant difference between the secure and loose conditions was only established at the high frequency range. Loosening of 2 mm was detected at driving frequencies of 850–1050 Hz, while 4-mm loosening was detected at 500–950 Hz. Therefore the harmonic ratio was clearly able to discern between the simulated conditions using both measurement methods.

The use of single density Sawbones block to mimic different loosening conditions was an attempt to simplify acetabular cup instability, which could be considered as a limitation. Additionally, the exaction method was positioned closer to the acetabular component than would be possible in a clinical setting. Moreover, the loosening conditions had only press-fit acetabular cups with hard shell components. Future experiments will try to overcome these limitations by moving towards a more clinically realistic setup. Initially, this will involve using a Sawbones hemi-pelvis with an implanted THR cup, followed by a combined pelvis and femur containing a complete THR [5]. On successful completion of these experiments a further aim would be to carry out a pilot clinical study.

5. Conclusion

This work has demonstrated that vibration analysis can be used to detect acetabular cup component loosening in a simplified *in vitro* model using either the accelerometer or ultrasound to measure output vibration. The harmonic ratio is a novel and useful parameter for comparing output signals to easily discern between secure and loose cups. Further experiments will be required to overcome current study limitations and achieve a more realistic setup for loosening scenarios.

Ethical approval

Not required.

Conflict of interest statement

There are no conflicts of interest to declare.

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Figure captions

Figure 1: Vibration analysis concept showing the difference between the secure and loose acetabular cup prostheses.

Figure 2: The Sawbones block showing the excitation and measurement methods.

Figure 3: The three simulated testing conditions of 0, 2, and 4 mm of loosening.

Figure 4: The experimental setup showing the Sawbones block, excitation, and measurement methods.

Figure 5: FFT spectrum analysis at 200 Hz showing the difference between the secure prosthesis, 2 mm loose condition, and 4 mm loose condition for the ultrasound and accelerometer readings.

Figure 6: The harmonic ratio of the different loosening conditions using an accelerometer and an ultrasound probe as the measurement methods. *Graphs a*, *c*, and *e* used an accelerometer for the loosening conditions of (0 mm, 2 mm, and 4 mm), (0 mm and 2 mm), and (0 mm and 4 mm), respectively. *Graphs b*, *d*, and *f* used an ultrasound for the loosening conditions of (0 mm, 2 mm and 4 mm), (0 mm and 2 mm), and (0 mm and 4 mm), respectively. *Mann-Whitney test $p < 0.05$.